TITLE: PLM pocH-100i Operating Procedure	**Doc #:** 10902
Section: \\Management System\PLM\Point of Care Testing\CBC Diff\	**Version:** 1.0 Current
Document Owner: ES Team Lead	**Effective Date:** 7/8/2013
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Purpose

This procedure provides instructions to perform blood analysis using the Sysmex pocH 100i in a point of care setting.

Abbreviations

CBC Complete Blood Count
EDTA Ethylenediaminetetraacetic Acid
HCT Hematocrit
HGB Hemoglobin
LYM Lymphocyte
Neut Neutrophil
MCHC Mean Cell Hemoglobin Concentration
TAC Technical Assistance Centre
MCH Mean Cell Hemoglobin
MCV Mean Cell Volume
MXD Mixed Cell
PLT Platelet
RBC Red Blood Cell
RDW Red Cell Distribution Width
WBC White Blood Cell

Materials

pocH-pack D: Analyzes approximately 30 samples

Description	Storage	Stability	Comments
pocH-pack D	• Unopened 1 - 30°C • On-board 15 - 30°C	• Expiry date • 60 days	• Replace cartridge if cloudiness or color change, occur
pocH-pack L	• Unopened 2-35 °C • Opened 15-30 °C.	• Expiry date • 90 days	• Replace if signs of contamination or instability • Do not use if it was frozen.
CELLCLEAN or filtered bleach	Original Container 15-30° C • Secondary Container	• Expiry date • 24 hours	• Always store in a dark place • Avoid exposure to direct sunlight

Reagents preparation: No preparation required

Supplies
• Thermal paper (CL6040)

Equipment
SYSMEX pocH-100*i* Automated Hematology Analyzer
Sysmex Sample tube adapter 13 mm cream colored (442-3031-8)
Sample tube adapter green colored- Control blood (442-3051-2)
Sysmex Reagent tray 367-2170-9

Sample

If samples are required for laboratory analysis refer to: *Laboratory Test Catalogue Collection & Shipping Requirements*

Sample type	Amount required	Storage	Stability
EDTA whole blood (4.0 ml Lavender tube)	• For collection- 1 mL or more of whole blood • For analysis- 15 µL	18 - 25°C	24 hours

Limitations:
Optimal draw is a tube drawn to capacity. For acceptable results, do NOT analyze a collection tube if it contains less than 1 ml of sample.

Sample retention:
Store sample in rack provided for laboratory retrieval and disposal

Specimen Rejection Criteria

• Insufficient amount of blood	• Clotted samples
• Greater than 24 hours at room temperature	• Hemolyzed samples
• Samples drawn above IV site	

Special Safety Precautions

"Routine Practices" as directed by Health Canada, must be considered as the level of care provided for all patients. Use Health Canada Guidelines for "Routine Practices" to avoid exposure to blood, body fluids and contaminated surfaces. All patient samples, as well as the materials they contact, are to be considered biohazardous and therefore capable of transmitting infection or cross contamination.
CELLCLEAN is a strong alkaline cleaning material. It should not come in contact with skin or clothing. If it happens, wash skin or clothing with plenty of water to avoid injury or damage.

Maintenance Complete *pocHi Maintenance Log* for all maintenance performed

1. Daily Maintenance

Laboratory will perform all other scheduled maintenance**.**

Step	Action
1.1	**Clean instrument surface** Clean the instrument surface and the touch panel using a soft dry cloth moistened with neutral detergent or isopropyl alcohol. **Note:** Do not use any organic solvent, acid, or alkaline agent as this will harm the instrument.
1.2	**Check instrument status** 1.2.1 Check to ensure sufficient reagent is on-board 1.2.3 Check status screen (if required) by: • Press "**Menu**" • Press **"Maint"** • Press **"Status Display"** • Check required fields **Note**: This information is requested when Sysmex TAC is contacted.
1.3	**Shutdown** must be performed at least every 24 hours Do not turn pocHi OFF without executing a proper shutdown as follows: 1.3.1 Press the **[Shutdown]** 1.3.2 Press the **[Execute]** 1.3.3 **Wait** for Shutdown completion screen to appear 1.3.4 **Turn OFF** using the main power switch on the right side of the instrument **Note:** Performing [Shutdown] prevents protein build-up. Protein build up will inhibit correct analysis results and may damage the instrument
1.4	**Check paper** Check that the paper supply is adequate **Replacement Procedure**: 1.4.1 Open the paper holder 1.4.2 Remove the tape (from new paper roll) 1.4.3 Insert paper into paper holder 1.4.4 Close the paper holder **Note**: • The printer cover must be closed ("clicking" sound). If the cover is not closed completely, an error message will be displayed • Insert the paper correctly. If inserted at an angle, the paper may jam

2. Periodic Maintenance

Step	Action
2.1	**Replace reagent** 2.1.1 Set bottles into holder 2.1.2 Remove caps 2.1.3 Insert container spout kits/ float switch into the correct bottle and reapply the caps 2.1.4 Connect the tubes to the appropriate nipples 2.1.5 Fix tubes together
2.2	**Dispose of waste** (Decontamination is a scheduled laboratory task) 2.2.1 Remove the cap from the full waste bottle. 2.2.2 Pull the float switch straight out to remove it 2.2.3 Dispose the waste fluid in designated sink 2.2.4 Clean the waste bottle out with water 2.2.5 Insert the float switch into the empty waste bottle 2.2.6 Apply the cap 2.2.7 Check that the tube is not bent. **Note:** The waste bottle must be secure and properly connected before operating the instrument or the waste discharge operation may fail.

Calibration

Indications

- Scheduled (every 6 months)
- Critical parts are replaced
- Controls show an unusual trend or are outside of acceptable limits and cannot be corrected by maintenance or troubleshooting.
  - Advised by pocH-100*i* Technical Assistance Center

Responsible Personnel

1. Laboratory staff

Quality Control

All **3** controls **must be run**

1. **Once a shift**
2. **After new reagents are loaded**
3. **After maintenance procedures**

Quality Control files will be updated by the laboratory as required
Record the date on each vial when **opening**

Control	Level	Storage	Stability	Frequency
EIGHTCHECK-3WP X-TRA	1	2 to 8°C	Unopened- Labeled expiration date Opened- 14 days	Once a shift
EIGHTCHECK-3WP X-TRA	2			
EIGHTCHECK-3WP X-TRA	3			

Note: Discard vial if left at room temperature (25°C) in excess of 12 hours

1. Procedure for Quality control

Note: Do not open the sample compartment while aspirating

Step	Action
1	**Equilibrate Control Blood to (18-30°C)** Remove a vial of control material from the refrigerator and equilibrate to room temperature (18-30°C) for 15 minutes before mixing.
2	**Prepare Control Blood** 2.1 Mix contents by rolling it back and forth between the palms 10 times 2.2 **Turn** the vial upside down **and roll** 10 more times 2.3 Repeat above steps eight times or for a total of **2 minutes** 2.4 Examine the bottom of the vial and confirming that there is no pellet of cells adhering to the bottom of the vial. -If there still is a pellet of cells, repeat steps 2.1 - 2.4
3	**Analyze control sample** 3.1 Press [**QC**] 3.2 **Select** the correct level and lot number for control sample to be analyzed 3.3 **Press [Push]** to **open** sample compartment 3.4 **Insert correct** adapter 3.5 Set the control blood into the **control blood adapter** 3.6 **Close** the sample compartment 3.7 Press [**Run**] 3.8 **Wait** for aspiration to complete • When '**Running**' is displayed, the sample position door can be opened and the sample can be removed safely. 3.9 Repeat **3.1** through **3.8** for remaining control levels 3.10 **Return controls** to refrigerator for storage
4	**Evaluate** control results If results are flagged **outside** the acceptable range – • **Do not** report results for that test • **Repeat** control flagged • **Record** incident on *pocHi Maintenance Log* If no results are flagged- • **Analyse** samples as required
5	**Place** control printouts in pocHi binder

Procedure

Note:
- An object (such as a pencil) under the sample compartment can obstruct the door opening mechanism.
- **Do not** force the sample tube into the sample adapter or force the sample adapter into the sample compartment.
- Use the [Push] lever above the sample compartment when opening the door
- Do not enter a sample ID as "0". (The analysis result will not be printed or stored)

2. Sample PROCEDURE (Analysis Time- 90 – 125 seconds)

Step	Action
2.1	**Collect** sample 2.1.1 **Collect** EDTA whole blood **sample** (4.0 ml Lavender tube) • Mix sample by gentle inversion 8-10 times **Note:** Mix the sample **promptly** after the blood is drawn. Mix samples **gently**. Insufficient or vigorous mixing may cause damage blood cells and inaccurate results 1.1.2 **Label** Specimen • Patient name, Patient MRN and/or HCN number • Time and date of collection • Initials of staff drawing blood
2.2	**Analyse** sample 1.2.1 **Press [SAMPLE ID]** 1.2.2 **Scan (**or manually enter**) Patient ID** 1.2.3 Press **[Push]** lever to **open** sample compartment 1.2.4 **Insert correct adapter** (Cream colored) 1.2.5 **Mix** sample by 10 gentle inversions 1.2.6 **Insert sample tube** into adapter 1.2.7 **Close** the sample compartment 1.2.8 Press [**Run**] 1.2.9 **Wait** for aspiration to complete • When '**Running**' is displayed, the sample position door can be opened and the sample can be removed safely. 1.2.10 **Wait for results** to print
2.3	**View** results for completeness and/or repeats according to *Reporting Results Chart* (Appendix 1)
2.4	**Attach** results to ***Point of Care Results Record*** *Form*. (Appendix 2)

Calculation

All required calculations are performed by the instrument. For specific information on calculations used, refer to *Sysmex pocH-100i Instructions for Use.*

Result Interpretation

All pocHi results are reviewed prior to attachment to *Point of Care Results Record*.

Send a specimen to the laboratory for analysis when:

1. Printed result have any of the following flags and procedural error is ruled out:

Flag	Description	Flag	Description
"**!**"	Value outside linearity limit	"**+++.+**"	Value exceeds display range
"*****.***"	Value could not be calculated because of analysis error	"---.-"	Value could not be calculated due to data error
"*****"	Result is unreliable		

2. As stated in *Ranges pocH 100i* (Appendix 1) for results that fall outside the Critical and/or action limits

3. If patient symptoms are inconsistent with results from pocHi and procedural error is ruled out

Expected Values

Refer to **Appendix 1** - ***Ranges pocH 100i***

Limitations

Known Interfering Substances

1. Specimens must be free of clots and fibrin strands.
2. Marked changes in plasma constituents (e.g. low sodium, extremely elevated glucose) may cause cells to swell or shrink. The blood to anticoagulant ratio is important.
3. Red cell fragments, microcytic RBC's or white cell cytoplasmic fragments may interfere with automated platelet counts.
4. Cold agglutinins produce spurious macrocytosis, elevated MCH's MCHC's, falsely decreased RBC counts and HCT's. Rare Warm agglutinins produce the same spurious results as a cold agglutinin.
5. Extremely elevated WBC's (>100 x 10^9/L) may cause turbidity and increase the hemoglobin.
6. Severely hemolyzed samples (in vitro) falsely decrease RBC and hematocrit. Recollect hemolyzed specimens.
7. Giant platelets and clumped platelets may falsely elevate the WBC count.

Limitations (continued)

8. Platelet clumping and/or "platelet satellitism" can occur in specimens collected in EDTA. This may falsely elevate the WBC and will falsely decrease the platelet count. Recollect the specimen in Sodium Citrate anticoagulant and multiply by a 1.1 dilution factor.
9. Abnormal paraproteins, lipemia, and jaundice can falsely increase the HGB, MCH and MCHC. When the MCHC is > 360 and one of the aforementioned substances are suspected, these parameters must not be charted. If clinically warranted, recollect the patient and test on a dedicated hematology analyzer.
10. Mixing a specimen excessively may affect the WBC differential.
11. Abnormal proteins as seen in Multiple Myeloma and Waldenstrom's macroglobulinemia may falsely increase the WBC count.
12. Fragmented RBC may cause a falsely low HCT value.
13. The hemoglobin method on this analyzer cannot detect sulfhemoglobin, or other unusual degradation products of hemoglobin.

Principle

WBC: DC detection method
RBC/PLT: Hydrodynamic Focusing DC detection method
HGB: Non-cyanide HGB method
HCT: RBC pulse height detection method

For a more detailed description please refer to Technical Background Information section in the *Instruction for Use Manual*

Clinical Utility

The CBC consists of a series of parameters used in the detection and monitoring of various disease states including, but not limited to anemia, leukemia, infections, inflammatory states and inherited hematological conditions.

Related Procedures and Documents

- *Laboratory Test Catalogue Collection & Shipping Requirements*
- *PLM Verification Handling Abnormal Results*
- *PLM Verification Review Criteria Job Aid*
- *Combined Point of Care Result Form*

Reference

- Instruction for use Manual, Sysmex Corporation, 2006 (www.sysmex.com)
- pocH-100i CLSI/NCCLS Procedure, 04-2009
- Cerner Millennium- CBC Reference Ranges
- Paradigm -PLM Verification Handling Abnormal Results
- Paradigm - PLM Verification Review Criteria Job Aid

Appendix 1

Ranges pocH 100i

Display range	
WBC 0.0 - 299.9 (× 103/µL)	HGB 0 - 25.0 (g/dL)
RBC 0.00 - 19.99 (× 106/µL)	PLT 0 - 1999 (× 103/µL)

Test	Units	Sex/AGE	Reference	Send sample to lab	CRITICAL
WBC	x 10^9/L	0 – 1 wk	9.4 – 26.0	< 3.5	<1.5 & >30.0
		1 wk – 3 mos	5.0 – 18.0		<1.5 & >30.0
		3 mos – 4 yrs	6.0 – 15.0		<1.5 & >30.0
		4 – 8 yrs	5.5 – 13.0		<1.5 & >30.0
		8 – 16 yrs	4.5 – 13.0		<1.5 & >30.0
		16 – 150 yrs	4.5 – 11.0		<1.5 & >30.0
RBC	x10^{12}/L	0 – 1 wk	4.00 – 6.60		
		1 – 2 wks	3.90 – 6.30		
		2 wks – 1 mos	3.60 – 6.20		
		1 – 2 mos	3.00 – 5.40		
		2 – 3 mos	2.70 – 4.90		
		3 – 6 mos	3.10 – 4.50		
		6 mos – 2 yrs	3.70 – 5.30		
		2 – 6 yrs	3.90 – 5.30		
		6 – 12 yrs	4.00 – 5.20		
		Male- 12 – 150 yrs	4.50 – 6.50		
		Female- 12 – 150 yrs	3.80 – 5.80		
HGB	g/L	0 – 1 wks	145 – 225	<70 or >180	<70
		1 – 2 wks	135 – 215		<70
		2 wks – 1 mos	125 – 205		<70
		1 – 2 mos	100 – 180		<70
		2 – 3 mos	90 – 140		<70
		3 - 6 mos	95 – 135		<70
		6 mos – 2 yrs	105 – 135		<70
		2 – 6 yrs	115 – 145		<70
		6 – 12 yrs	115 – 155		<70
		Male- 12 – 150 yrs	140 – 180		<70
		Female- 12 – 150 yrs	120 – 160		<70
HCT	Fraction	0 – 1 wks	.450 - .670		
		1 – 2 wks	.420 - .660		
		2 wks – 1 mos	.390 - .630		
		1 – 2 mos	.310 - .550		
		2 – 3 mos	.280 - .420		
		3 – 6 mos	.290 - .410		
		6 mos – 2 yrs	.330 - .390		
		2 – 6 yrs	.340 - .400		
		6 – 12 yrs	.350 - .450		
		Male- 12 – 150 yrs	.420 - .540		
		Female- 12 – 150 yrs	.370 - .470		
MCV	fL	0 – 1 wks	95.0 – 121.0	< 70 or > 110	

Test	Units	Sex/AGE	Reference	Send sample to lab	CRITICAL
		1 – 2 wks	88.0 – 126.0		
		2 wks – 1 mos	86.0 – 124.0		
		1 – 2 mos	85.0 – 123.0		
		2 – 3 mos	77.0 – 115.0		
		3 – 6 mos	74.0 – 108.0		
		6 mos – 2 yrs	70.0 – 86.0		
		2 – 6 yrs	75.0 – 87.0		
		6 – 12 yrs	77.0 – 95.0		
		12 – 150 yrs	80.0 – 97.0		
MCH	pg	0 – 2 mos	28.0 – 40.0		
		2 – 3 mos	26.0 – 34.0		
		3 – 6 mos	25.0 – 35.0		
		6 mos – 2 yrs	23.0 – 31.0		
		2 – 6 yrs	24.0 – 30.0		
		6 – 12 yrs	25.0 – 33.0		
		12 – 150 yrs	28.0 – 32.0		
MCHC	g/L	0 – 1 mos	280 – 360	> 360	
		1 – 3 mos	290 – 360		
		3 mos – 2 yrs	300 – 360		
		2 – 12 yrs	310 – 360		
		12 – 150 yrs	320 – 360		
RDW	%	0 – 6 mos	13.5 – 16.0	> 22.0	
		6 mos – 15 yrs	12.7 – 13.4		
		15 – 150 yrs	11.5 – 14.5		
PLT	x 10^9/L	0 – 150 yrs	150 – 350	<100 or > 1000	<30
MPV	fL	Male- 0 – 1 yrs	5.2 – 9.1		
		Female- 0 – 5 yrs	6.0 – 9.4		
		Male- 1 – 5 yrs	5.9 – 9.5		
		Male- 5 – 10 yrs	6.0 – 10.0		
		Female- 5 – 10 yrs	6.1 – 10.3		
		10 – 150 yrs	7.4 - 10.4		
MXD	%	NA	NA		
LYMPH	%	0 – 1 wks	22.0 – 40.0		
		1 – 2 wks	31.0 – 51.0		
		2 wks – 3 mos	38.0 – 58.0		
		3 – 6 mos	49.0 – 69.0		
		6 mos – 2 yrs	51.0 – 71.0		
		2 – 4 yrs	49.0 – 69.0		
		4 – 6 yrs	40.0 – 60.0		
		6 – 8 yrs	32.0 – 52.0		
		8 – 16 yrs	28.0 – 48.0		
		16 – 150 yrs	15.0 – 41.0		
NEUT	%	0 – 9 yrs	25.0 – 65.0		
		9 – 150 yrs	45.0 – 70.0		
LYMPH	#	0 – 150 yrs	1.5 – 4.0	>5.0	
MXD	#		0.2 – 1.2	> 2.5	
NEUT	#	0 – 150 yrs	2.0 – 7.5	<1.0 or > 20.0	

Appendix 2

Patient Information:

Name: Health Card (PMI)#:

Med. Rec. #: Physician:

Loc/Room/Bed: Sex/Age/DOB:

Place patient identification label here or record information to the right

Collection Information:

Date and time of collection: _____

Collected by: _____

Test	Range	Units
Sodium	136 -144	mmol/L
Potassium	3.6 - 5.1	mmol/L
Chloride	101 -111	mmol/L
Glucose (AC)	3.6-5.6	mmol/L
Creatinine	Male 54 -113 Female 37-96	µmol/L
Ionized Calcium	1.07-1.41	mmol/L
TCO2	22 - 32	mmol/L
Hematocrit	Male 0.420 - 0.540 Female 0.370 - 0.470	Fraction
Anion Gap*	4-16	mmol/L
Troponin	*Negative<0.05*	*ng/ml*
INR	0.8 – 1.2	
WBC	4.5 – 11.0	x 10E9/L
RBC	Male 4.50 – 6.50 Female 3.80 – 5.80	10E12/L
HGB	Male 4.50 – 6.50 Female 3.80 – 5.80	mmol/L
HCT	Male .420 - .540 Female .370 - .470	Fraction
MCV	80.0 – 97.0	fL
MCH	28.0 – 32.0	pg
MCHC	320 – 360	g/L
RDW	11.5 – 14.5	%
PLT	150 – 350	10E9/L
MPV	7.4 - 10.4	fL
LYM %	15.0 – 41.0	%
MXD %	M 4.0 – 15.7	%
LYM#	1.5 – 4.0	#
MXD#	0.2 – 1.2	#
NEUT#	2.0 – 7.5	#

Attach instrument printout

(If not indicated on printout please complete)

Analysis Performed by:

_____

* Calculation for Anion Gap = Na – (Cl + TCO2)

Reference ranges stated are for the adult population. Patients, who do not fall within the adult population, please refer to appropriate procedure.